REMARKS

Examiner Wehbé , SPE Reynolds, and Practice Specialist Brian Stanton are thanked for their assistance and for courtesies extended during the telephonic interview of December 3, 2003. Reconsideration and withdrawal of the remaining rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which are believed to place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 16-62, 64-66 and 68-107 are pending. Claims 68-107 were allowed; claims, even certain allowed claims, are amended to improve the language, without changing scope (e.g., claim 96 is amended so it is not a duplicate of claim 95, and certain allowed independent claims are amended to recite that the sequence encoding the immunogen is operably linked to the promoter, as the immunogen encoded by that sequence would not itself be operably linked to the promoter). Certain dependent claims are amended to recite "eukaryotic promoter".

Support for the recitation "eukaryotic promoter" can be found on page 7, line 18, of the specification, as well as at original claim 9. No new matter is added. It is also believed that the herewith amendments do not introduce any additional claims, or any new issues requiring any further search or examination, such that this paper presents no impediment to its consideration and entry.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 16-62, 64-66 and 68-107 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-80 of U.S. Patent No. 6,451,770. A terminal disclaimer with respect to U.S. Patent No. 6,451,770 was filed on July 17, 2003. The Examiner is thanked for indicating in the Advisory Action that the double patenting rejection has been overcome.

III. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claims 16-62 and 64-66 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Examiner is thanked for acknowledging that the specification is enabling for an immunogenic composition or vaccine comprising a plasmid encoding an immunogen from a bovine pathogen, operably linked to a viral promoter, administered using a liquid jet intradermal administration apparatus, and methods for inducing an immunological response or vaccinating against a bovine pathogen. The Office Action argues that the specification is not enabling for the use any promoter to drive expression of a bovine pathogen immunogen, and that it would require undue experimentation to use non-viral promoters in the instant invention.

It is respectfully pointed out that claims are drawn to inducing an immunological response in a bovine. The invention involves the surprising result that a liquid jet device for intradermal administration, which was designed for porcine animals, aka "the pigjet", also is effective in bovines. As was discussed in the December 3, 2003 interview, one would be able to get some immunological response with any promoter. The level of expression is not material to the claims, provided that there is enough expression to elicit an immunological response. And, it is respectfully submitted that, a case has NOT been made by the PTO that an immunological response would NOT be elicited in a bovine by a composition administered to the bovine by the pigjet. Rather, Applicants have demonstrated that compositions administered to a bovine by the pigjet, e.g., plasmid compositions wherein the plasmid contains and expresses a coding sequence, such as a coding sequence operably linked to a eukaryotic promoter, as recited in the claims, certainly achieves the goal of eliciting an immunological response.

Indeed, Applicants are not claiming a DNA plasmid vaccine or immunological composition *per se*, but rather, methods for inducing an immunological response or vaccinating involving the use of the pigjet. Having pioneered the use of the pigjet in bovines for the administration of plasmid vaccine or immunological compositions, Applicants are entitled to claims of the breadth presented.

A pioneer patent has been defined as one which performs a function never performed by an earlier invention". 239 F.2d 339, 345 (5th Cir. 1986). The Courts have held that, as an incentive to invent and to the prompt, early disclosure of inventions, as well as a reward for having broken new ground, pioneer patents are entitled to broad claims to the broad concept

disclosed. *In re Hogan*, 194 U.S.P.Q. 527, 537 (CCPA, 1977). The Court reasoned in *In re Hogan* that:

> The PTO has not challenged appellants' assertion that their 1953 application enabled those skilled in the art in 1953 to make and use "a solid polymer" as described in claim 13. Appellants disclosed, as the only then existing way to make such a polymer, a method of making the crystalline form. To now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system. There cannot, in an effective patent system, be such a burden placed on the right to broad claims. To restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restriction is merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts, the constitutional purpose of the patent laws.

Id.

Not only can claims to a pioneering invention encompass embodiments that are not specifically disclosed, they can also encompass embodiments not contemplated by the inventor at the time the application is filed. *See Phillips Petroleum Co. v. U.S. Steel*, 6 U.S.P.Q.2d 1065, 1074 (D.Del. 1987), *aff'd* 9 U.S.P.Q.2d 1461 (Fed. Cir. 1989) (an inventor may properly claim subject matter than later turns out to be beyond his actual research, so long as his research enables one skilled in the art to make and use the claimed invention as it was understood at the filing date).

The first paragraph of Section 112 does not require a specific example of everything within the scope of a broad claim. *In re Anderson*, 176 U.S.P.Q. 331, 333 (C.C.P.A 1973). This is true even in an unpredictable art. *In re Obukowitz*, 27 U.S.P.Q. 2d 1063, 1067 (BOPAI 1993). Such a requirement would have an adverse affect on the patent system. *See In re Angstadt and Griffin*, 190 U.S.P.Q. 214, 218 (C.C.P.A., 1976) (to require a disclosure of every species covered by a claim would force an inventor to carry out a prohibitive number of experiments, and would allow potential infringes to avoid literal infringement by merely finding an analogous embodiment not expressly disclosed)); *In re Goffe*, 191 U.S.P.Q. 429, 431 ("To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for

'preferred' materials in a process . . . . would not serve the constitutional purpose of promoting progress in the useful arts.").

It seems that the PTO is having an issue as to whether some embodiments within the claims may be inoperative. Firstly, as discussed above, Applicants have demonstrated that an immunological response can indeed be elicited by embodiments of the invention and that there is no reason to doubt that other embodiments would likewise be operative.

Secondly, the Courts have repeatedly held that even if some claimed combinations are inoperative, the claims are not necessarily invalid. For example, in *Atlas Powder Co. v. E.I. Dupont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984), the accused infringer argued that the disclosure of the patent in suit (directed to an ammonium nitrate-fuel oil emulsion used as a blasting agent) listed numerous ingredients which could be combined to form thousands of emulsions, some of them inoperable, with no commensurate teaching as to which combinations would work. The Federal Circuit stated:

> The district court held it would have been impossible for [the applicant] to list all operable emulsions and exclude the inoperable ones. Further, it found such list unnecessary, because one skilled in the art would know how to select a salt and fuel and then apply "Bancroft's Rule" to determine the proper emulsifier. Bancroft's Rule was found by the district court to be a "basic principle of emulsion chemistry," and DuPont has not shown that finding to be clearly erroneous.
>
> We agree with the district court's conclusion on enablement. Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid.

Id. at 414-15.

Similary, in *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974), the Examiner had rejected a claim directed to the improvement of the process of exchanging deuterium for hydrogen in organic compounds, on the ground that the specification failed to support the scope of the claims. He alleged that the claims encompassed the use of certain organic compounds in the deuteration process which might undergo interfering reactions with, e.g., deuterium peroxide, and for which suitable operating conditions were not adequately disclosed. The Board affirmed the rejection of the claim.

The CCPA reversed the decision of the Board, stating:

> [T]here has been no challenge whatever to appellants' repeated assertions that the starting materials containing the so-called "reactive groups" are deuterated. The hypothesized oxidation or even destruction of the original compounds per se, by splitting or other mechanism, cannot be considered an indication of the inoperability of the replacement reaction. The only valid assumption is that the form of the final deuterated product might differ from that of the starting material. Such a change is not inconsistent with claim language . . . .
>
> Although the board also hypothesized that the peroxide might oxidize the Adams catalyst necessary for the deuteration into inactivity, we agree with appellants that is implicit in the claims that the conditions of the process have not been met unless the catalyst is present and inactive as a catalyst. Requiring a recitation in the claims of the specific deuterium peroxide proportions employed in the examples to insure that activity would be an unnecessary limitation. Disclosure in the specification sufficient to enable practice of the invention by one skilled in the art, taking into consideration obvious modifications of the reactant ratios of specific examples, is all that is required. It is not a function of the claims to specifically exclude either possible inoperative substances or ineffective reactant proportions.

Id. at 47-48 (underlining added).

Although "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed by invalid", *Atlas Powder Co.*, 224 U.S.P.Q. at 414, it is not necessary to specifically disclose a large number of operative embodiments to outweigh the possibility of some inoperative embodiments.

For example, in *Ex parte Obukowitz,* the Board of Patent Appeals and Interferences reversed the rejection of a claim to a method of combatting plant insect pests by inserting DNA encoding the protein toxin of *Bacillus thuringiensis* into any plant-colonizing bacteria. The Board found that the applicant had rebutted any *prima facie* case of non-enablement made by the Examiner, based on the disclosure in the specification of successful testing in two bacterial species, an expert declaration describing successful testing in a third species, and a declaration from another expert in the field asserting that "many other" plant colonizing bacteria could be so transformed, and that "most bacteria containing the gene would be expected to kill or impair the growth of insects in a plant environment". *Id.* at 1066.

There are also several cases which approach the problem of inoperative embodiments by reasoning that, the objective having been stated in the preamble, any compositions which are inoperative for that objective are inherently outside the scope of the claims. For example, in *In re Anderson*, 176 U.S.P.Q 331 (C.C.P.A. 1973), the court reversed the board's rejection of claims directed to a laminated dressing containing a medicament as "broader than warranted by the disclosure" because the term medicament could include materials such as anticoagulants or debiding agents, which would prevent the hemostatic action required of the dressing. The Court stated:

> The board, seemingly, is demanding a claim limitation to operative medicaments in operative quantity. We think that dependent claims such as the above, which merely add a limitation to the two-layer combination dressing by calling for medication in the primary layer, are inherently limited - by common sense if nothing else - to such medication as would be useful in the particular application. No one of ordinary skill would use any other kind of medicament and there is no practical way to restrict the claim language so as to exclude all inoperative or deleterious medicaments other than by the addition of such redundant terms as "suitable" or "operative for the purposes described." We dealt with similar arguments in In re Myers, 56 CCPA 1129, 410 F.2d 420, 161 USPQ 668, 672 (1969), and in dealing with an undue breadth rejection said:
>
> If every element in a mechanical combination claim were required to be so specific as to exclude materials known to be inoperative and which even those not skilled in the art would not try, the claims would fail to comply with 35 U.S.C. 112 [second paragraph] because they would be so detailed as to obscure, rather than [to] particularly point out and distinctly claim, the invention.

Id. at 334-35 (emphasis added).

The Court of Customs & Patent Appeals used similar reasoning in reversing the decision of the Board in *In re Geerdes*, 180 U.S.P.Q. 789 (C.C.P.A. 1974). The claims in that case were directed to a method of producing foamed polymer compositions, and they had been rejected under 112, second paragraph, because they were allegedly "inclusive of materials which would not apparently be operative in the claimed process." The Board held that materials not operative in the claimed process were not included in the claims:

> [W]e cannot agree with the board's determination that the claims are inclusive of materials which would not apparently be operative in the claimed process. The claims call for producing a foam and solidifying the foam. Having stated the objective (foamed product)

> together with the process steps, use of materials which might prevent achievement of the objective (by rendering the process inoperative) can hardly be said to be within the scope of the claims. We also note that the board's determination of apparent inoperativeness is unsupported by reasons or evidence. Of course, it is possible to argue that process claims encompass inoperative embodiments on the premise of unrealistic or vague assumtions, but that is not a valid basis for rejection.

Id. at 793 (emphasis in original).

There is no question that the application, particularly by the application's Examples and Figures, teaches, describes, supports, and enables the claimed invention; and, that Applicants, in the present record, and in the record of the parent application, have demonstrated a sufficient quantity of operative embodiments and have presented proper claim language that avoids inoperative embodiments, such that the claims encompass numerous operative embodiments and/or avoid inoperative embodiments, and it is clear that NO undue experimentation is needed to practice the invention as claimed.

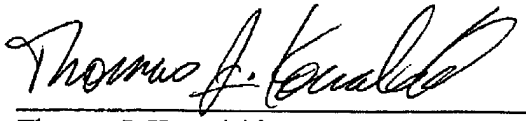
Accordingly, the claims meet the requirements of Section 112, first paragraph, and reconsideration and withdrawal of the rejection are requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance, or in better condition for appeal. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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